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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/897,871	07/02/2001	Heather A. Bowen-Leaver	2870/485	1385

7590 12/05/2001

Estelle J. Tsevdos, Ph.D., J.D.
KENYON & KENYON
One Broadway
New York, NY 10004

EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1619

2

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/897,871

Applicant(s)

BOWEN-LEAVER ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P r i d f r R p l y

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-6, 11, 12, and 16 are rejected under 35 U.S.C. 112, first paragraph, because the written description does not show that the inventor had possession of, as of the filing date of the application relied on, the specific subject matter later claimed by him or her.

In the instant case, the specification does not describe the invention which is claimed to contain emulsifiers in the amount less than 5 percent by weight of the total composition. Instead, in the specification, cosmetic components that are conventionally used as emulsifiers are instead termed as "thickeners" or "surfactants" and still used in the compositions such that the total amount of these ingredients that emulsify at the surface level of water and oil exceeds 5 percent by weight of the composition. For example, specification categorizes cetearyl alcohol, cetyl alcohol, and polyoxyethylene glycol, which are conventionally known as emulsifiers in the art, as thickeners that still may be added in the composition in the amount up to 1 wt %. See spec. p. 9, [00025-26]. Even applicants' specification also discloses that some surfactants, including silicone surfactants, also act as emulsifiers at the surface level of the oil and water in the composition. See spec. p. 10, [00028]. Furthermore, it is examiner's position that one of ordinary skill in the art would also consider "volatile silicone oil" of claim 4, including "cyclomethicone" of claim 5, also function as "emulsifiers". See Bungard et al. (U.S. Pat. No. 6,045,781, stating cyclomethicone is a silicone emulsifier). Thus,

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examiner concludes that the specification does not demonstrate that the inventors had possession of the composition containing less than 5 wt % of emulsifier.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 6, and 9, the term "difference in complex viscosity" is vague and indefinite. The term is not explained in the specification nor is it apparent to one of ordinary skill in the art what it means.

In claim 7, the phrase "shearing the oil-in-water emulsion at least two consecutive times" is vague and indefinite because the scope of the patent protection sought is not clear. The term "sheared three times" in claim 8 is also vague and indefinite for an analogous reason.

Claim 13 recites the limitation "the pre-emulsion" in claim 7. There is insufficient antecedent basis for this limitation in the claim.

The remaining claims are rejected as depending on indefinite claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

I. Claims 1-6, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Claudelli (U.S. Pat. No. 4,026,818) in view of Simonnet (U.S. Pat. No. 6,120,778).

Claudelli teaches transparent ringing gels for cosmetic use, comprising mineral oil, water, and 5-9 percent by weight of (2 ethyl 1,3-dihydroxy) 2-propyl oleamide. See col. 1, lines 5 – 63. The reference teaches transparent gels are obtained due to the small particle size of the dispersed droplet, which allows rapid absorption on skin of active ingredients contained in the composition. The reference teaches using low ratios of emulsifier to oil could be achieved, which is less costly. The reference is silent as to the actual value of the viscosity of the ringing gel. However, given the teaching of the vibration of the particles within the gel, examiner views that the “difference in complex viscosity” at a given oscillation stress is a measurement of varied viscosity present in the ringing gel of the invention. Claudelli is silent as to the size of the oil globules in the composition and also lacks the teaching of using silicone oil in the emulsion.

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Simonnet teaches oil-in-water nanoemulsion based on silicone surfactants, wherein the oil globules have a mean size of less than 100 nm. See abstract; col. 2, lines 1 - 26. The reference teaches that the composition may be formulated into a gel form. See col. 5, lines 32 - 36. Simonnet teaches the process of producing the invention by high-pressure homogenization at a pressure greater than 10^8 Pa, or at 1500 bars with 7 passes, in col. 4, line 63 - col. 6, line 9.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Claudelli by incorporating silicone phase in the emulsion and applying high shear force to produce oil-in-water nanoemulsion gel, as suggested by Simonnet, because of the expectation of successfully producing a transparent gel composition with large amount oil with enhanced penetration action of active components into the skin.

II. Claims 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simonnet and Claudelli as applied to claims 1-6 and 15 above, and further in view of Kakoki et al. (U.S. Pat. No. 5,162,377) ("Kakoki").

Simonnet and Claudelli, discussed above, lack an explicit teaching of the shearing process of instant claims 7 and 8.

Kakoki teaches producing transparent emulsion cosmetic composition by high-shearing treatment. In the reference high shearing force treatment is carried out by high-pressure homogenization using emulsifiers such as Microfluidizer which is used in the present invention, or Manthon Gaulin, under a pressure of 500 psi or more. See col. 4, line 44 - col. 5, line 23. The Examples 4-13 shows treating the emulsion

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compositions with Manthon Gaulin at least 5-10 times to obtain transparent aqueous compositions.

Given the teaching in the combined references of the high-pressure homogenization process in producing nanoemulsion ringing gel compositions, one of ordinary skill in the art at the time the invention was made to have would have known looked for prior arts such as Kakoki for specific types of homogenizer, and method steps to carry out the process to make the said composition, and treated the pre-emulsion with high shearing force to produce transparent compositions.

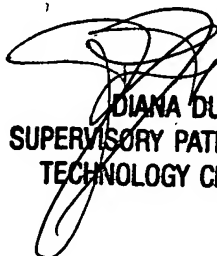
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-305-3593.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner
November 28, 2001


DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600